



01P-0130/CP1

Food and Drug Administration
Rockville MD 20857

0024 01 AUG 21 22:07

AUG 20 2001

Pharmaceutical Associates, Inc.
Attention: Kaye B. McDonald
201 Delaware Street
Greenville, SC 29605

Docket No. 01P-0130/CP1

Dear Ms. McDonald:

This is in response to your petition filed on March 14, 2001, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Hydrocodone Bitartrate and Acetaminophen Elixir, 10 mg/650 mg per 15 mL. The reference listed drug product to which you refer in your petition is Hydrocodone Bitartrate and Acetaminophen Elixir, 7.5 mg/500 mg per 15 mL, approved under ANDA 81-051, held by Mikart, Inc.

Your request involves a change in strength of both the acetaminophen component and the hydrocodone bitartrate component from that of the listed drug product (i.e., from hydrocodone bitartrate 7.5 mg/15 mL to 10 mg/15 mL and from acetaminophen 500 mg/15 mL to acetaminophen 650 mg/15 mL). The changes you request are the type of changes that are authorized under the Federal Food, Drug, and Cosmetic Act (Act).

We have reviewed your petition under Section 505(j)(2)(C) of the Act and have determined that it is approved. This letter represents the Agency's determination that an ANDA may be submitted for the above-referenced drug product.

Under Section 505(j)(2)(C)(i) of the Act, the Agency must approve a petition seeking a strength which differs from the strength of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing strength.

The Agency finds that the change in strength for the specific proposed drug product does not pose questions of safety or effectiveness because the uses and route of administration of the proposed drug product are the same as that of the listed drug product. In addition, when an ANDA is submitted for your proposed drug product, the proposed labeling should reflect the maximum number of doses per day that can be administered for your proposed drug product. The total daily dose of the acetaminophen component should not exceed the maximum total daily dose for adults of 4000 mg established by the Agency for its safe and effective range. Please refer to the Tentative Final Monograph for Internal Analgesic, Antipyretic, and Antirheumatic

01P-0130

1

PAV 1

01P-0130/CP1

Drug Products for Over-the-Counter Human Use (53 FR 46204, November 16, 1988) for information regarding the maximum daily dose of Acetaminophen. In addition, a single dose of Acetaminophen may not exceed 1000 mg. The total daily dose for Hydrocodone Bitartrate may not exceed 60 mg.

The Agency concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug product can be expected to have the same therapeutic effect as the listed reference drug product.

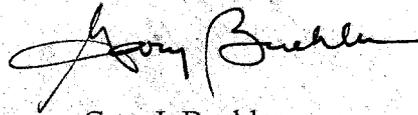
The approval of this petition to allow an ANDA to be submitted for the above-referenced drug product does not mean that the Agency has determined that an ANDA will be approved for the drug product. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the Agency.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug product will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you submit your protocol to the Office of Generic Drugs, Division of Bioequivalence for this drug product prior to the submission of your ANDA. During the review of your application, the Agency may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the one upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,



Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research